K001451

MAY 1 8 2000

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA
Tel: +1 (219) 267 8143
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Summary of Safety and Effectiveness

NAME OF SPONSOR:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) CONTACT:

Janet G. Johnson, RAC
Sr. Regulatory Associate
Phone: (219) 371-4907
FAX: (219) 371-4940

TRADE NAME:

DePuy Contour Unicompartmental Knee Prosthesis

COMMON NAME:

Unicompartmental Knee Prosthesis

CLASSIFICATION:

888.3530 Knee joint, femorotibial metal/polymer semi-constrained cemented prosthesis

DEVICE PRODUCT CODE:

87 HRY

SUBSTANTIALLY EQUIVALENT DEVICE:

DePuy Keane Unicompartmental Knee System
K910807

DEVICE DESCRIPTION:

The Contour Unicompartmental Knee Prosthesis all poly tibial component is manufactured from UHMWPE and is designed to articulate with the Contour Unicompartmental Knee femoral component. Like the Keane Unicompartmental Knee tibial component the fixation surface of the Contour Unicompartmental knee tibial component consists of a waffle pattern of undercuts.
The Contour all poly tibial component is available in 3 AP sizes, 32, 35, and 38.5 mm. All three tibial component sizes are designed to articulate with all sizes of the Contour Unicompartmental Knee femoral components.

Summary of Safety and Effectiveness (Continued)

INDICATIONS FOR USE:

The DePuy Contour Unicompartmental Knee Prosthesis is indicated for use as the tibial component in a unicompartmental knee replacement for patients suffering from severe pain and disability due to structural damage caused by advanced femoral-tibial unicompartmental degenerative arthritis resulting from primary osteoarthritis or trauma. The device is also indicated for use in patients with osteochondritis dissecans of the tibial condyle. The system is indicated for use only with bone cement.

SUBSTANTIAL EQUIVALENCE:

The fundamental scientific technologies of the DePuy Contour Unicompartmental Knee Prosthesis have not changed from the FDA cleared (K910807) DePuy Keane Unicompartmental Knee System. They have the same intended use, indications, materials, method of manufacture, and similar designs. DePuy believes that the DePuy Contour Unicompartmental Knee Prosthesis is substantially equivalent to the FDA cleared (K910807) DePuy Keane Unicompartmental Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Ms. Janet G. Johnson, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
A Johnson & Johnson Company
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K001451
Trade Name: DePuy Contour Unicompartmental Knee Prosthesis
Regulatory Class: II
Product Code: HRY
Dated: May 5, 2000
Received: May 9, 2000

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001451

Device Name: DePuy Contour Unicompartmental Knee Prosthesis

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation

NRW for CMW

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K001451

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)